AUG - 1 2000

K000704

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510(k) SUMMARY

Submitter's name: Duracare Medical Equipment, L.C.
1411 SE 10th St.
Cape Coral, FL 33990
(941) 772-4279

Date summary prepared: January 14, 2000

Device name:

Proprietary name: WIN-1 Tango™
Common or usual name: Power chair.
Classification name: Powered wheelchair, Class II, 21 CFR 890.3860.

Legally marketed device for substantial equivalence comparison:

Zippy submitted by Pillar Technology, Inc. and cleared for marketing under 510(k) #K972851.

Description of the device:

The WIN-1 Tango is a powered wheelchair for use both indoors and outdoors. It is battery powered, has two 0.25 horsepower motors, and a controller unit with joystick. It is designed for a single rider who controls the speed and direction of the chair's movement with the joystick. It can be disassembled for transport and a battery charger is supplied as an accessory.

Intended use of device:

The intended use of the Tango is to provide mobility for a person restricted to a sitting position.

Technological characteristics:

The device features and use parameters of the Tango and the Zippy are quite similar. Each is battery operated, uses two batteries, has two motors, and has an automatic braking system. Similar batteries and battery chargers are used in each wheelchair. There are slight variations in the use parameters of the wheelchairs such as different maximum slopes, ground clearances, and speed ranges.

Testing conducted:

Testing was conducted to relevant portions of *ANSI/RESNA Wheelchairs Vol.2 1998 Draft.* Flammability testing of the seat material was also documented. The results of all testing were included in the subject 510(k) submission.

Performance testing:

Comparative performance testing and clinical evaluations were not submitted as part of this 510(k).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 2000

Duracare Medical Equipment, L.C.
Mr. Robert S. McQuate
c/o R. S. McQuate & Associates, Inc.
3636 E. Columbine Drive
Phoenix, Arizona 85032

Re: K000204
Trade Name: WIN–1 Tango Power Chair
Regulatory Class: II
Product Code: ITI
Dated: May 4, 2000
Received: May 5, 2000

Dear Mr. McQuate:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Lochner

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K000207

Device name: WIN-1 Tango

Indications for Use:

To provide mobility for a person restricted to a sitting position.

(Please do not write below this line)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lochner

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000204

Prescription Use _____ OR Over-The-Counter Use X